Maury Bandurraga-MM To: FDADockets@oc.fda.gov

Cc: bandurraga.mm@pg.com

01/19/2001 06:06 PM Subject: Docket No. 94P-0036

Please accept for filing the following comments submitted by The Procter & Gamble Company. An original and 2 copies of these comments are also being sent by first class mail. Please contact me with any questions at the email address above or at 513-634-4137.



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Dr. Maury Bandurraga The Procter & Gamble Company FAX 513-634-1813

Procter&Gamble

The Procter & Gamble Company Winton Hill Technical Center 6071 Center Hill Avenue, Cincinnati, Ohio 45224-1703

January 19, 2000

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Dockets Management Branch (HFA-305) Food and Drug Administration Room 1061 Parklawn Building 5630 Fishers Lane Rockville, MD 20852 (301) 827-6860

Re: [Docket No. 94P-0036]

Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and

6107

Health Claims; Reopening of Comment Period. 65 Federal Register 75888, December 5, 2000.

The Procter & Gamble Company submits the following comments on the docket referenced above regarding trans fatty acid nutrition labeling and nutrient content claims. Procter & Gamble (P&G) previously filed comments to this docket in April 2000. P&G is a global manufacturer of a wide variety of consumer products, including foods and beverages, and as such has significant interest in nutrition labeling and the ability to use nutrient content claims for those products, and the impact of differing trans labeling proposals in common market areas such as NAFTA.

On December 5, 2000 (65 FR 75888), FDA reopened the comment period on its trans fatty acids labeling proposed rule to allow for additional comment on two issues related to nutrient content claims: the possible definitions for a "reduced trans fat" claim and a "reduced saturated and trans fats" claim.

P&G supports GMA and NFPA comments submitted on 1/19/01 on the November 22 FDA proposal on the nutrient content claim definitions for "reduced trans fat" and "reduced saturated fat". Thus we agree with the parallel definitions of "reduced trans fat" and "reduced saturated fat" as proposed by GMA and NFPA to define a 25% reduction in the claimed fat type, holding the other at no increase, compared to the reference food.

P&G also strongly supports GMA and NFPA comments to provide for an additional nutrient content claim for a combination reduction of trans fat and saturated fat. This combination claim for overall 25% net reduction in "combined trans plus saturated fat" would greatly support the formulation flexibility needed to achieve the functionality and taste endpoints desired by food formulators and consumers while balancing net reduction in the combined trans and saturated fat levels, since the two types of fatty acids appear to act similarly in the body based on the science to date.

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P&G also supports GMA, NFPA, and ISEO comments submitted to FDA on 1/19/01 requesting FDA to work closely with Health Canada to develop either mutual recognition or a completely harmonized North American food label.

Based on the recent Canadian trans proposal, the most notable exception to a harmonized approach is the proposed labeling presentation for trans fat. FDA has proposed that the amount of trans fat be combined with saturated fat and be presented with a asterisk after saturated fat referring to a footnote on the trans amount within the saturated fat declaration, at the bottom of the panel. Canada proposes a separate line for trans fat but a combined Daily Value for saturated plus trans. We strongly support GMA, NFPA, and ISEO positions that the trans formats for U.S. and Canada should be consistent or mutually recognized by the other country. Different presentation standards in the U.S. and Canada will be burdensome to manufacturers in both countries engaged in cross-border trade and would necessitate dual label inventories.

Therefore, P&G encourages both Health Canada and FDA to cooperate to harmonize the trans labeling presentation and claims approach or to provide the flexibility to permit either labeling approach in both countries.

Thank you for the opportunity to comment on these important issues.

Sincerely,

Maury M. Bandurraga, Ph.D.

Regulatory Affairs Manager

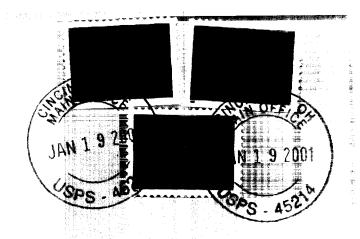
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